



# Homeland Security

## Statement for the Record

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*before the*

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**Subcommittee on Emerging Threats, Cybersecurity, and Science &**  
**Technology**  
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## **INTRODUCTION**

Good afternoon, Mr. Chairman, Ranking Member McCaul and distinguished members of the Subcommittee. Thank you for the opportunity to describe the role of the Department of Homeland Security (DHS) under Project BioShield.

## **PROJECT BIOSHIELD OVERVIEW**

The Project BioShield Act of 2004 (PL 108-276) amended the Public Health Service Act to provide protections and countermeasures against biological, chemical, radiological, or nuclear agents that may be used in a terrorist attack against the United States by giving the National Institutes of Health contracting flexibility, infrastructure improvements, expediting the scientific peer review process, and expanding the Food and Drug Administration authority to allow the use of unapproved medical countermeasures in a declared emergency.

Today, Project BioShield is a \$5.6 billion program designed to stimulate the development of medical countermeasures for natural or chemical, biological, radiological, and nuclear threats for which there are no existing commercial markets. Both DHS and the Department of Health and Human Services (HHS) have major responsibilities under the Project BioShield Act.

## **DHS RESPONSIBILITIES UNDER PROJECT BIOSHIELD**

In accordance with section 319F-2(c)(2) of the Project BioShield Act of 2004, it is the DHS' responsibility, in consultation with HHS and other agencies, to assess current and emerging threats of natural or chemical, biological, radiological, and nuclear agents, and to determine which agents present a significant material threat to the U.S. population.

To fulfill this responsibility, DHS conducted detailed modeling of threats, vulnerabilities, and consequences for various plausible scenarios of a terrorist attack. As a result of this work, DHS identified 12 biological threats, plus radiological and nuclear devices, meeting the statutory requirement to merit a Material Threat Determination (MTD). As of September 20, 2006, DHS completed the MTD list based on detailed assessments of the agents with inputs from the intelligence, law-enforcement, scientific, and public-health communities. This MTD list will be updated, as needed, based on the outcomes of biennial Chemical, Biological, Radiological and Nuclear (CBRN) risk assessments.

Accompanying each MTD is a Population Threat Assessment (PTA). The PTA estimates the size of the population exposed by the agents identified in the MTDs to gauge the impact on the population and national infrastructure if that particular agent was released for a given high consequence plausible scenario. As of December 2006, DHS completed the PTAs of all MTDs. Moreover, DHS remains engaged in ongoing threat assessments

and communicates regularly with our Federal partners to ensure we have accurate, up-to-date material threat information.

## **THE TRANSITION OF RESPONSIBILITY TO HHS**

Once the MTDs are issued and PTAs are completed for any given threat, the results are shared with HHS for consequence modeling to support the procurement of appropriate countermeasures. HHS created the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), under the direction of the HHS Assistant Secretary for Preparedness and Response, to identify, develop and acquire medical countermeasures that will improve public health emergency preparedness, including preventing and mitigating the adverse health consequences associated with the priority CBRN threats identified by DHS. On the PHEMCE Executive Governance Board (EGB), whose members are the Assistant Secretary for Preparedness and Response, the Centers for Disease Control and Prevention, the National Institutes of Health, and the Food and Drug Administration. DHS serves as an ex officio member along with the Department of Defense, the Homeland Security Council, the Office of Science and Technology Policy, the Office of Management and Budget (OMB), and the Office of the Vice President.

Upon identification of countermeasures that meet the eligibility requirements to warrant use of the Special Reserve Fund (SRF) the Secretary of DHS and the Secretary of HHS jointly request that OMB release funds to HHS from the SRF, to acquire the countermeasures. DHS has worked with HHS to expedite the implementation of BioShield by clarifying roles and responsibilities and by establishing mechanisms to improve efficiencies in this process.

Under section 319F-2(c) (7) (C) of the Public Health Service Act, as amended, HHS is ultimately responsible for managing the countermeasure procurement process including the negotiation of terms and entering into contracts for research, development, acquisition, procurement, storage and distribution of countermeasures.

## **THE FUTURE OF THE BIOSHIELD ENTERPRISE**

DHS is confident that the Secretary of HHS' plan for the future of BioShield will result in addressing the appropriate needs of the Nation in terms of preparedness. In order to address the above, improvement in transparency to the program's stakeholders was in evidence at the meeting held in September of 2006. The Pandemic and All-Hazards Preparedness Act of 2006 (PL 109-417) provided a missing piece to HHS' ability to stimulate the development of needed countermeasures with the authorization of the Biomedical Advanced Research & Development Authority to help companies through the advanced development process, if funded appropriately. The formation of the Public Health Emergency Medical Countermeasures Enterprise will provide the HHS Secretary with expert advice to make his decisions in collaboration with the interagency and its respective stakeholders. The PHEMCE strategic plan is a key step in defining, in a transparent way, how BioShield will carry out its business moving forward.

What is still missing from the enterprise is a commitment from the Nation's medical industry as a whole to invest in our biodefense. We must find ways to involve the private sector more broadly in this priority for our Nation. The ability of our private sector to thrive depends on their safety and security. It would be a worthy investment in time, talent and treasure for companies large and small to come to the table, even without the promise of large returns on their monetary investments. We thank the Congress for giving us a wide range of innovative acquisition and other authorities to pave the way for increased private investment. We will need to rely on the ingenuity and creativity of the American enterprise to reach a condition of security from bioterrorism.

## **CONCLUSION**

Thank you, Mr. Chairman, for the opportunity to speak to you today on the role of DHS under the Project BioShield Act. I am happy to answer any questions the Subcommittee may have.